Philips Medical Systems Nederland B.V.
Veenpluis 4-6, 5684-PC, Best
The Netherlands

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510(k) summary

JUL 29 2011

The following information is submitted in accordance with the requirements of 21CFR 807.92.

Identification of manufacturer

Company:..... Philips Medical Systems Nederland B.V.
Address:..... Veenpluis 4-6,
5684-PC, Best, The Netherlands
Registration number:..... 3003768277

Identification of U.S. designated agent

Company:..... Philips Medical Systems
Address:..... 22100 Bothell Everett Highway
Bothell, WA 98021-8431, U.S.A.
Registration number:..... 1217116

Identification of official correspondent

Name:..... Lynn Harmer
Position:..... Senior Manager, Regulatory Affairs
Telephone:..... (425) 487-7312
Date prepared:..... April 27, 2011

Device identification

Trade name:..... Philips
Device name:..... HeartNavigator
Regulation description:..... Picture archiving and communications system
Regulation number:..... 21CFR 892.2050
Class:..... II
Product code:..... 90L--LZ

Legally marketed devices

Trade names:..... Philips EP navigator, Philips Xper CT
Manufacturer:..... Philips
510(k) numbers:..... K101311, K060749

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Device description

HeartNavigator Release 1 uses cardiac 3D image data of the patient as a source for procedure planning.
In the procedure planning phase, the tool supports the user to:

- Identify and Visualize relevant anatomical structures in the 3D image data.
- Determine and store the X-ray system viewing angles to be used during the procedure.
- Evaluate device placement for the current treatment.

During the procedure the tool allows the user to:

- Visualize the relevant anatomical structures in the 3D image data.
- Recall stored viewing angles and assists the user to move to these angles.
- Register the 3D image data to the X-ray system.
- See an overlay image of the 3D image data and the live fluoroscopy on a separate monitor in addition to the normal monitor showing the conventional live X-ray without alteration.

Intended use

HeartNavigator Release 1 is a tool which assists the user with procedure planning and provides live image guidance in addition to conventional live fluoroscopy guidance for structural heart disease procedures.

Indications for Use:

Medical purpose:
HeartNavigator Release 1 is a tool which assists the user with procedure planning and provides live image guidance in addition to conventional live fluoroscopy guidance for structural heart disease procedures.

Patient population:
HeartNavigator Release 1 is intended to be used in combination with Allura Xper systems for treating the entire population of patients with structural heart diseases via interventional technologies.

Operator profile:
The user is a clinical specialist who is fully skilled and qualified to perform the structural heart disease procedure and is responsible for sound clinical judgment and for applying the best clinical procedure. The user may also be a nurse assisting the clinical specialist.
The user must have received adequate training in its safe intended and effective use before operating the HeartNavigator.

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Technological characteristics

HeartNavigator Release 1 image software processing algorithms are executed on a PC based hardware platform

Summary of testing

HeartNavigator Release 1 complies with standards as detailed in this premarket submission. Clinical evaluation was performed to show safety and effectiveness of HeartNavigator Release 1 in the intended clinical environment. Non-clinical verification and validation tests were performed relative to the requirement specifications and risk management results, specifically including software verification, validation and DICOM conformance testing. Corresponding clinical evaluation report and test results are included in this submission.

Conclusion:..... HeartNavigator Release 1 is substantially equivalent to the currently legally marketed devices.

This opinion is based on the following:

- HeartNavigator Release 1 does not introduce new technology
- HeartNavigator Release 1 does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems Nederland B.V.
% Lynn Harmer
Sr. Manager, IS Regulatory Affairs
Philips Healthcare
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

JUL 29 2011

Re: K111245
Trade/Device Name: HeartNavigator Release 1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 2, 2011
Received: May 3, 2011

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

Device Name

HeartNavigator

Indications for Use

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Indications for Use Statement

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Prescription Use __yes_____ AND/OR Over-The-Counter Use __No___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111245